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7590 04/14/2008 Henricks Slavin & Holmes LLP			EXAMINER	
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Suite 200 El Segundo, CA 90245			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 09/548,465 BENCINI ET AL. Office Action Summary Examiner Art Unit LAURA C. SCHELL 3767 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 28 January 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 44-48.50-54.65.66.68-71 and 73-96 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 44-48.50-54.65.66.68-71 and 73-96 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner, Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☐ All b) ☐ Some * c) ☐ None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 1/28/08.

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

51 Notice of Informal Patent Application

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DETAILED ACTION

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filted in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 47, 48, 50, 51 and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Lundquist et al. (US Patent No. 5,336,182). Lundquist discloses an apparatus (Figs. 1-6, for example), comprising: an elongated body (Fig. 1, generally labeled as 30) defining a proximal portion (near 80) and a distal portion (near 160) including a wall defining an inner surface (Fig. 4 discloses the inner surface of 30), an outer surface (Fig. 4 discloses the outer surface of 40) and a lumen extending from the proximal portion to an aperture in the distal portion (Fig. 35 discloses an embodiment with a lumen leading to an aperture); a stiffening member associated with the distal portion of the elongate body (230 is clearly stiffer than the flexible catheter in which it resides as Lundquist discloses that the steering wire (150) and stiffening member (230) are soldered together therefore disclosing that these are two metal members); an antitear device (190) positioned adjacent to at least a portion of the stiffening member (Figs. 2-4) and configured to prevent the stiffening member from tearing through the elongate body when the stiffening member bends (190 constitutes the same device as the

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applicant's anti-tear device, and furthermore, provides the same function of the anti-tear device, to spread out the force and stress placed on the steering wire); and a steering wire (120/150), which is not connected to the anti-tear device and which is not located within the stiffening member (Figs. 2-4 disclose that the steering wire is attached to the stiffening member, not located within the stiffening member), having a distal portion operably connected to the distal portion of the elongate body (Fig. 4 discloses that the very distal portion comprises an anchoring member which the steering wire is attached to via 230; please note that the claim language does not state that the steering wire must be directly attached to the elongate body).

In reference to claim 48, Lundquist discloses that the anti-tear device is secured to the stiffening member (via 220).

In reference to claims 50 and 51, Lundquist discloses that the anti-tear device comprises a tubular member (190 is tubular) and comprises a slot (220).

In reference to claim 66, Lundquist discloses that the elongate body defines a diameter (Fig. 4) and the stiffening member and the distal portion of the steering wire are substantially diametrically proposed from one another (Fig. 2).

Claim 68 is rejected under 35 U.S.C. 102(b) as being anticipated by Lundquist et al. (US Patent No. 5,336,182). Lundquist discloses an apparatus (Figs. 1-6), comprising: an elongated body (Fig. 1, generally labeled as 30) defining a proximal portion (near 80) and a distal portion (near 160) including a wall defining an inner

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surface (Fig. 4 discloses the inner surface of 30), an outer surface (Fig. 4 discloses the outer surface of 40) and a lumen extending from the proximal portion to an aperture in the distal portion (Fig. 35 discloses an embodiment with a lumen leading to an aperture); a stiffening member (230 is clearly stiffer than the flexible catheter in which it resides as Lundquist discloses that the steering wire (150) and stiffening member (230) are soldered together therefore disclosing that these are two metal members) associated with the distal portion of the elongate body (Fig. 4) such that the stiffening member will apply a force over an elongate body surface area when the stiffening member is bent (Figs. 3 and 4); anti-tear means (190 constitutes the same device as the applicant's anti-tear device, and furthermore, provides the same function of the antitear device, to spread out the force and stress placed on the steering wire), associated with the stiffening member (via slot 220), for increasing the elongate body surface area over which the force is applied when the stiffening member is bent to prevent the stiffening member from tearing through the elongate body (Figs. 2-4); and a steering wire (120/150), which is not connected to the anti-tear means, having a distal portion operably connected to the distal portion of the elongate body (connected to the elongate body via its connection to 230 as 230 is connected to the very distal end of the elongate body as seen in Fig. 4. Please note that the claim language does not require the steering wire to be directly connected to the elongate body); wherein the stiffening member and the distal portion of the steering wire are substantially diametrically opposed from one another (Fig. 2 discloses an attachment point at 260 where it can be

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said that they are diametrically opposed, as the claims do not specify with respect to what diameter they are diametrically opposed).

Claims 69, 73, 74 and 92 are rejected under 35 U.S.C. 102(b) as being anticipated by Lundquist et al. (US Patent No. 5,336,182). Lundquist discloses an apparatus (Figs. 1-6), comprising: an elongated body (Fig. 1, generally labeled as 30) defining a proximal portion (near 80) and a distal portion (near 160) including a wall defining an inner surface (Fig. 4 discloses the inner surface of 30), an outer surface (Fig. 4 discloses the outer surface of 40) and a lumen extending from the proximal portion to an aperture in the distal portion (Fig. 35 discloses an embodiment with a lumen leading to an aperture); a steering wire (120/150) having a distal portion (near the distal end of 260); an anchoring member (Fig. 4, discloses a weld as 260 and therefore can be considered an anchoring member as it anchors two members together; please note that the claim language does not require any further structure of the anchoring member, and therefore the welding point 260 anticipates the claim language) associated with the distal portion of the elongate body and secured to the steering wire (260 is secured to the steering wire and located at the distal end of the device); a stiffening member (230 is clearly stiffer than the flexible catheter in which it resides as Lundquist discloses that the steering wire (150) and stiffening member (230) are soldered together therefore disclosing that these are two metal members) associated with the distal portion of the elongate body (Fig. 4) and defining a distal end (Fig. 4), the distal end of the stiffening member being directly secured to the anchoring member (Fig.

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4 discloses that the stiffening member 230 is secured to anchoring member 260); and a substantially tubular member (190) secured to the stiffening member (secured via 220 which is an interference fit. If this was not a secure fit the parts would move relative to each other during operation of the device and impair if not prevent the operation of the device. Please also note that Applicant has not claimed how they are directly secured together) and defining a continuous length in a direction parallel to the longitudinal axis (Figs. 2 and 3) and a wall thickness, the continuous length being substantially greater than the wall thickness (Figs. 2 and 3 disclose that the length of 190 is longer than the wall thickness); wherein the wire is movable relative to the substantially tubular member (Figs. 2 and 3 disclose that the steering wire is not connected to the tubular member and Fig. 3 in particular discloses that the wire is movable relative to tubular member both longitudinally and radially).

In reference to claim 73, Lundquist discloses a handle (Fig. 1, 110) operably connected to the elongate body and to the steering wire, adapted to pull the steering wire relative to the elongate body (col. 5, line 67 through col. 6, line 2).

In reference to claim 74, Lundquist discloses that the steering wire extends to the proximal portion of the elongate body and is movable relative to the proximal portion of the elongate body (col. 5, line 67 through col. 6, line 2).

In reference to claim 92, Lundquist discloses that the anchoring member (260) is directly secured to the steering wire (120/150; see Fig. 4).

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Claims 70, 93 and 94 are rejected under 35 U.S.C. 102(b) as being anticipated by Lundquist et al. (US Patent No. 5.336.182). Lundquist discloses an apparatus (Figs. 1-6), comprising: an elongated body (Fig. 1, generally labeled as 30) defining a proximal portion (near 80) and a distal portion (near 160) including a wall defining an inner surface (Fig. 4 discloses the inner surface of 30), an outer surface (Fig. 4 discloses the outer surface of 40) and a lumen extending from the proximal portion to an aperture in the distal portion (Fig. 35 discloses an embodiment with a lumen leading to an aperture); a steering wire (120/150) having a distal portion (near the distal end of 230); an anchoring member (Fig. 4 discloses weld joint 260 which anchors two elements together and therefore can be considered the anchoring member; please note that the claim language does not require any further structure of the anchoring member, and therefore the weld 260 anticipates the claim language) associated with the distal portion of the elongate body and secured to the steering wire (260 is located at the distal end of the device and is secured to the steering wire 120/150); a stiffening member (230 is clearly stiffer than the flexible catheter in which it resides as Lundquist discloses that the steering wire (150) and stiffening member (230) are soldered together therefore disclosing that these are two metal members) associated with the distal portion of the elongate body (Fig. 4) and defining a distal end (Fig. 4), the distal end of the stiffening member being directly secured to the anchoring member (Fig. 4 discloses that the distal end of the stiffening member 230 is directly secured to the anchoring member 260); and a substantially tubular member (190), including a slot (220), secured to the stiffening member (secured via 220) and defining a continuous length in a direction parallel to the

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longitudinal axis (Figs. 2 and 3) and a wall thickness, the continuous length being substantially greater than the wall thickness (Figs. 2 and 3 disclose that the length of 190 is longer than the wall thickness).

In reference to claim 93, Lundquist discloses that the anchoring member (260) is directly secured to the steering wire (120/150 Fig. 4).

In reference to claim 94, Lundquist discloses that the substantially tubular member (190) is directly secured to the stiffening member (secured via 220 which is an interference fit. If this was not a secure fit the parts would move relative to each other during operation of the device and impair if not prevent the operation of the device. Please also note that Applicant has not claimed how they are directly secured together).

Claims 71, 95 and 96 are rejected under 35 U.S.C. 102(b) as being anticipated by Lundquist et al. (US Patent No. 5,336,182). Lundquist discloses an apparatus (Figs. 1-6), comprising: an elongated body (Fig. 1, generally labeled as 30) defining a proximal portion (near 80) and a distal portion (near 160) including a wall defining an inner surface (Fig. 4 discloses the inner surface of 30), an outer surface (Fig. 4 discloses the outer surface of 40) and a lumen extending from the proximal portion to an aperture in the distal portion (Fig. 35 discloses an embodiment with a lumen leading to an aperture); a steering wire (120/150) having a distal portion (near the distal end of 260); an anchoring member (Fig. 4 discloses weld 260 which anchors two members together and therefore can be considered an anchoring member) associated with the distal

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portion of the elongate body and secured to the steering wire (260 is located at the distal end of the device and is secured to the steering wire); a stiffening member (230 is clearly stiffer than the flexible catheter in which it resides as Lundquist discloses that the steering wire (150) and stiffening member (230) are soldered together therefore disclosing that these are two metal members) associated with the distal portion of the elongate body (Fig. 4) and defining a distal end (Fig. 4), the distal end of the stiffening member being directly secured to the anchoring member (Fig 4. discloses that stiffening member 230 is directly secured to anchoring member 260); and a substantially tubular member (190), which extends less than completely around the longitudinal axis (Figs. 2 and 3 disclose that the tubular member does not extend completely around the longitudinal axis because of slot 220), secured to the stiffening member (secured via 220) and defining a continuous length in a direction parallel to the longitudinal axis (Figs. 2 and 3) and a wall thickness, the continuous length being substantially greater than the wall thickness (Figs. 2 and 3 disclose that the length of 190 is longer than the wall thickness).

In reference to claim 95, Lundquist discloses that the anchoring member is directly secured to the steering wire (anchoring member 260 is directly secured to steering wire 120/150 as seen in Fig. 4).

In reference to claim 96, Lundquist discloses that the substantially tubular member (190) is directly secured to the stiffening member (secured via 220 which is an interference fit. If this was not a secure fit the parts would move relative to each other

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during operation of the device and impair if not prevent the operation of the device.

Please also note that Applicant has not claimed how they are directly secured together).

Claims 45, 46 and 79 are rejected under 35 U.S.C. 102(b) as being anticipated by Umeda (US Patent No. 5,255,668). Umeda discloses an apparatus (figs. 1-5) comprising: an elongate body (9) defining a proximal portion (near 50) and a distal portion (near 40) and including a wall defining an inner surface, an outer surface and a lumen extending from the proximal portion to an aperture in the distal portion (35); a steering wire (8a/8b) having a distal portion (near 40); an anchoring member (40 is connected to the tip and connected to 8a/8b as well as 10 via 20) of the elongate body. configured such that it does not obstruct the aperture in the distal portion of the elongate body (Fig. 5 discloses that 40 is a tube so that it does not obstruct 35), and directly secured to the steering wire (col. 6, line 68 through col. 7, line 3); means, directly connected to the anchoring member for preventing compression of the elongate body distal portion during bending of the elongate body distal portion (10); and a tubular member that is a partial circle in cross-section (50, because of slots 51a and 51b, this cross section is a partial circle) and has a slot (51a/51b) positioned relative to the means for preventing compression so as to prevent the means for preventing compression from tearing through the elongate body when the means for preventing compression bends (this can be considered the anti-tear device equivalent to the

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applicant's anti-tear device, and furthermore, provides the same function of the anti-tear device, to spread out the force and stress placed on the steering wire).

In reference to claim 46, Umeda discloses that a portion of the steering wire is positioned within the slot (Fig. 2 discloses that the steering wires 8a/8b are positioned within the slots 51a/51b similar to the arrangement depicted in Fig. 5).

In reference to claim 79, Umeda discloses that the elongate body defines a longitudinal axis (Figs. 1 and 2); the steering wire and the means for preventing compression are radially offset from the longitudinal axis (Fig. 2); and the steering wire and the means for preventing compression are substantially diametrically opposed from one another (Fig. 2).

Claims 52-54 and 86 are rejected under 35 U.S.C. 102(b) as being anticipated by Umeda (US Patent No. 5,255,668). Umeda discloses an apparatus (figs. 1-5) comprising: an elongate body (9) defining a proximal portion (near 50) and a distal portion (near 40) and including a wall defining an inner surface, an outer surface and a lumen extending from the proximal portion to an aperture in the distal portion (35); a steering wire (8a/8b) having a distal portion (near 40) operably connected to the distal portion of the elongate body (connected to 40 which is connected to the elongate body; Figs. 2 and 4); a stiffening member (10) associated with the distal portion of the elongate body (Fig. 2); and a substantially c-shaped anti-tear device (50, because of slots 51a and 51b, this cross section is a partial circle/c-shaped) associated with the stiffening member (this can be considered the anti-tear device equivalent to the

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applicant's anti-tear device, and furthermore, provides the same function of the anti-tear device, to spread out the force and stress placed on the steering wire); wherein a portion of the steering wire is positioned within the slot (Fig. 2 discloses that the steering wires 8a/8b are positioned within the slots 51a/51b similar to the arrangement depicted in Fig. 5).

In reference to claim 53, Umeda discloses that the elongate body defines a longitudinal axis and the stiffening member extends less than entirely around the longitudinal axis (Fig. 2).

In reference to claim 54, Umeda discloses that the anti-tear device extends further around the longitudinal axis that the stiffening member (Fig. 2).

In reference to claim 86, Umeda discloses that the elongate body defines a longitudinal axis (Fig. 2); the steering wire and the stiffening member are radially offset from the longitudinal axis (Fig. 2); and the steering wire and the stiffening member are substantially diametrically opposed from one another (Fig. 2).

Claim 65 is rejected under 35 U.S.C. 102(e) as being anticipated by Matsuura et al. (US Patent No. 6,450,948). Matsuura discloses an apparatus (Figs. 1-13 for example) comprising: an elongate body (40) defining a proximal portion (near 22) and a distal portion (near 28) and including a wall defining an inner surface, an outer surface and a lumen extending from the proximal portion to an aperture in the distal portion (Fig.

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1 discloses the aperture as the opening in 40 which allows 28 to extend from and Fig. 4 discloses that the lumen is 34, also seen in Fig. 1); a steering wire (56 in the embodiment in Figs. 11 and 12 it is labeled as 356) having a distal portion that is located within the elongate body wall between the inner surface and the outer surface (Figs. 2, 3, 4, 6, 12 and 13 disclose that the puller wire 56/356 is located within the body wall; col. 3, lines 58-61) and is operably connected to the distal portion of the elongate body (Fig. 4 discloses that the distal end of 56 is embedded in the distal portion of the elongate body; col. 4, lines 12-14); a stiffening member (54a, 54b/354a, 354b) associated with the distal portion of the elongated body and defining a proximal end (the proximal end can be considered the end connected to 50a/350a); and an anti-tear device (50a/350a, this can be considered the anti-tear device equivalent to the applicant's anti-tear device, and furthermore, provides the same function of the anti-tear device, to spread out the force and stress placed on the steering wire) defining a proximal end (end furthest from 54/354) and a distal end (end closest to 54/354). secured to the proximal end of the stiffening member (Figs. 4 and 11) such that the proximal end of the anti-tear device is located within the distal portion of the elongate body; wherein the elongate body defines a distal end (Fig. 1) and at least a portion of the stiffening member is located proximal of the distal end of the elongate body (Figs. 1, 2, 4); and wherein the steering wire is not directly connected to the anti-tear device (Fig. 4 discloses that the steering wire passes through anti-tear device freely; col. 4, lines 6-9 and col. 4, lines 14-17).

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In reference to claim 87, Matsuura discloses that the stiffening member is located within the elongate body wall between the inner surface and the outer surface (col. 3, lines 58-61).

In reference to claim 88, Matsuura discloses that the anti-tear device is located within the elongate body wall between the inner surface and the outer surface (col. 3, lines 58-61).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 75-78 and 83-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Umeda (US Patent No. 5,255,668) in view of Matsuura et al. (US Patent No. 6,450,948). Umeda discloses the device substantially as claimed except for the steering wire, stiffening member and anti-tear device being located in the body wall.

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Matsuura, however, discloses that the steering wire (56/356), stiffening member (54/354) and the anti-tear device (50a/350a) are located in the body wall (col. 3, lines 58-61). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Umeda by placing the steering wire, stiffening member and the anti-tear device in the body wall as taught by Umeda so that the size of the lumen is larger and object-free in order to allow more versatility in use of the device.

Claims 80-82 and 89-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundquist et al. (US Patent No. 5,336,182) in view of Matsuura et al. (US Patent No. 6,450,948). Lundquist discloses the device substantially as claimed except for the steering wire, stiffening member and anti-tear device being located in the body wall. Matsuura, however, discloses that the steering wire (56/356), stiffening member (54/354) and the anti-tear device (50a/350a) are located in the body wall (col. 3, lines 58-61). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Lundquist by placing the steering wire, stiffening member and the anti-tear device in the body wall as taught by Matsuura so that the size of the lumen is larger and object-free in order to allow more versatility in use of the device.

Response to Arguments

Applicant's arguments with respect to claims 45-48, 50-54, 65-66, 68-71, 73-96 have been considered but are moot in view of the new ground(s) of rejection.

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In reference Applicant's arguments that element 260 in the Lundquist reference could not be interpreted as an stiffening member, the examiner has reviewed her rejection and the reference and realized that a typographical error was made and used reference number 260 to refer to member 230 (the stiffening member). The correction has been applied to the rejection of the claims above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/ Examiner, Art Unit 3767 /Kevin C. Sirmons/ Supervisory Patent Examiner, Art Unit 3767